Complete Summary

GUIDELINE TITLE

2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Smith TJ, Khatcheressian J, Lyman GH, Ozer H, Armitage JO, Balducci L, Bennett CL, Cantor SB, Crawford J, Cross SJ, Demetri G, Desch CE, Pizzo PA, Schiffer CA, Schwartzberg L, Somerfield MR, Somlo G, Wade JC, Wade JL, Winn RJ, Wozniak AJ, Wolff AC. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol 2006 Jul 1;24(19):3187-205. [128 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Ozer H, Armitage JO, Bennett CL, Crawford J, Demetri GD, Pizzo PA, Schiffer CA, Smith TJ, Somlo G, Wade JC, Wade JL, Winn RJ, Wozniak AJ, Somerfield MR. 2000 update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based, clinical practice guidelines. American Society of Clinical Oncology Growth Factors Expert Panel. J Clin Oncol 2000 Oct 15; 18(20): 3558-85.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Cancer

- Febrile neutropenia
- Hematopoietic malignancies
- Acute lymphocytic leukemia
- Acute myeloid leukemia
- Myelodysplastic syndromes
- Recurrent leukemia
- Neutropenic complications of cytotoxic treatments

GUIDELINE CATEGORY

Prevention Treatment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Patients Physicians

GUIDELINE OBJECTIVE(S)

To update the 2000 American Society of Clinical Oncology guideline on the use of hematopoietic colony-stimulating factors (CSF)

TARGET POPULATION

Adults (including the elderly) and children with cancer undergoing cytotoxic treatment (i.e., myelosuppressive chemotherapy, myeloablative chemotherapy and bone marrow transplant)

INTERVENTIONS AND PRACTICES CONSIDERED

Administration of hematopoietic colony-stimulating factors:

- Granulocyte colony-stimulating factor (G-CSF; filgrastim)
- Granulocyte-macrophage colony-stimulating factor (GM-CSF; sargramostim)
- Pegylated G-CSF (pegfilgrastim)

MAJOR OUTCOMES CONSIDERED

- Overall or disease-free survival
- Quality of life
- Toxicity
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For the 2005 update, a methodology similar to that applied in the original American Society of Clinical Oncology (ASCO) practice guidelines for use of hematopoietic growth factors was used. Pertinent information published from 1999 through September 2005 was reviewed. The Medline database (National Library of Medicine, Bethesda, MD) was searched to identify relevant information from the published literature for this update. A series of searches was conducted using the medical subject headings or text words, "granulocyte colony-stimulating factors," "granulocyte-macrophage colony-stimulating factors," "filgrastim," "lenograstim," "sargramostim," and "pegfilgrastim." These terms were combined with the study design-related subject headings or text words (in truncated forms to allow for variations of the root word): "meta-analysis," "random," and "phase III;" with the subject heading "drug administration schedule" and the text word "dose dense;" and with the text word, "child." Search results were limited to human studies and English-language articles. The Cochrane Library was searched with the phrase, "colony-stimulating factors." Directed searches based on the bibliographies of primary articles were also performed. Finally, Update Committee members contributed articles from their personal collections. Update Committee members reviewed the resulting abstracts and titles that corresponded to their assigned section.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Update Committee had four face-to-face meetings to consider the evidence for each of the 2005 Recommendations. The Update Committee formulated recommendations based on improvements in survival, quality of life, toxicity reduction and cost-effectiveness.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Impact of Colony-Stimulating Factors (CSFs) on Health Care Costs

In the original guideline and subsequent updates, the use of colony-stimulating factors (CSFs) could be justified on economic grounds if the rate of febrile neutropenia (FN) approached 40%, which was coincidentally the same as the clinical threshold for use of CSFs. With the new clinical threshold of benefit at a febrile neutropenia rate of 20%, and evidence of reduction in infection-related mortality, the Update Committee noted that CSFs should be used when indicated for clinical reasons, not economic ones. There was substantial discussion on the role of the Update Committee in limiting access to expensive but important drugs, the current threshold at which CSFs would be cost saving, and the impact of CSFs on health care costs. A study evaluated the efficacy and cost of prophylactic CSF in elderly patients with aggressive lymphoma treated with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) chemotherapy. While response rates, overall survival, and event-free survival were no different between the CHOP and CHOP-CSF arms, total hospital costs were higher for patients treated with CHOP-CSF compared with CHOP alone Even a low, fixed dose of CSF reduced FN rates. Given the low cost of a hospital day in the Netherlands (a few hundred dollars, not \$2,500 as in the US), their conclusions hold for there alone. A better trial would have used enough CSF to allow dose-dense therapy and collected resource utilization to allow other countries to plug in their numbers. Further research into the cost implications of CSF use is warranted. The CSF Update Committee recognized that these are expensive agents. As stated explicitly above, when available, alternative regimens offering equivalent efficacy, but not requiring CSF support, should be utilized.

Recently published data suggest that, when compared with standard CSF dosing, less frequent CSF dosing schedules may equally prevent neutropenia and chemotherapy dose delay and cause less bone pain and fever. This trial was a nonrandomized, observational study; its results should be considered hypothesis generating. And, as stated in another study, because the uncertainty of

benefits/harms of alternative treatment options is high and the benefit-harm ratio is unclear, a high level of evidentiary standards, such as a randomized clinical trial comparing standard versus alternative CSF dosing schedules, is needed. If proven to be equally efficacious, less frequent CSF dosing could have a significant impact on the cost of treatment.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

For the 2005 update, the guideline was circulated in draft form to the Update Committee for review and approval. The American Society of Clinical Oncology's (ASCO's) Health Services Committee and the ASCO Board of Directors also reviewed the final document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

<u>Recommendations for the Use of Hematopoietic Colony-Stimulating</u> Factors Treatment

Primary Prophylaxis

General Circumstances

Primary prophylaxis is recommended for the prevention of febrile neutropenia (FN) in patients who have a high risk of FN based on age, medical history, disease characteristics, and myelotoxicity of the chemotherapy regimen. For "dose dense" regimens, colony-stimulating factors (CSFs) are required and recommended. Clinical trial data support the use of CSF when the risk of febrile neutropenia is in the range of 20% or higher. In the absence of special circumstances, most commonly used regimens have risks of FN of <20%. In making the decision to use prophylactic CSF or not, oncologists should consider not only the optimal chemotherapy regimen but also the individual patient risk factors and the intention of treatment, that is, curative, prolongation of life, or symptom control and palliation. Examples of appropriate use in the curative setting include adjuvant treatment of early-stage breast cancer with more intensive regimens such as docetaxel, doxorubicin, and cyclophosphamide (TAC) or fluorouracil, epirubicin, and cyclophosphamide (FEC100) or the use of cyclophosphamide, adriamycin, vincristine, and prednisone (CHOP) or CHOP-like regimens in older patients with aggressive non-Hodgkin's lymphoma.

Specific Circumstances

Clinicians may occasionally be faced with patients who might benefit from relatively nonmyelosuppressive chemotherapy but who have potential risk factors for febrile neutropenia or infection because of bone marrow compromise or comorbidity. It is possible that primary CSF administration may be exceptionally

warranted in patients at higher risk for chemotherapy-induced infectious complications, even though the data supporting such use are not conclusive. Certain clinical factors predispose to increased complications from prolonged neutropenia, including: patient age greater than 65 years; poor performance status; previous episodes of FN; extensive prior treatment including large radiation ports; administration of combined chemoradiotherapy; bone marrow involvement by tumor producing cytopenias; poor nutritional status; the presence of open wounds or active infections; more advanced cancer, as well as other serious comorbidities. In such situations primary prophylaxis with CSF is often appropriate even with regimens with FN rates of < 20%. The special circumstances have always been part of the American Society of Clinical Oncology's (ASCO's) CSF guidelines, in recognition that there are patient factors that predict for the rate and severity of febrile neutropenia. These special circumstances have been maintained from previous versions of the guideline. The rate at which the use of CSFs should be considered has changed from 40% to 20%, consistent with the new evidence that demonstrates efficacy in reducing febrile neutropenia rates when the risk is approximately 20%.

Secondary Prophylaxis

Secondary prophylaxis with CSFs is recommended for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. In many clinical situations, dose reduction or delay may be a reasonable alternative.

Patients with Neutropenia Who Are Afebrile

CSFs should not be routinely used for patients with neutropenia who are afebrile.

Therapeutic Use of CSFs

Patients with Neutropenia Who Are Febrile

CSFs should not be routinely used as adjunctive treatment with antibiotic therapy for patients with fever and neutropenia. However, CSFs should be considered in patients with fever and neutropenia who are at high risk for infection-associated complications, or who have prognostic factors that are predictive of poor clinical outcomes. High-risk features include expected prolonged (>10 days) and profound (<0.1 x 10⁹/L) neutropenia, age greater than 65 years, uncontrolled primary disease, pneumonia, hypotension and multi-organ dysfunction (sepsis syndrome), invasive fungal infection, or being hospitalized at the time of the development of fever.

Use of CSFs to Increase Dose Intensity or Dose Density

Use of CSFs allows a modest to moderate increase in dose-density and/or dose-intensity of chemotherapy regimens. Available data would suggest a survival benefit from the use of dose-dense (but not dose-intense) regimens with CSF support in a few specific settings (e.g., node-positive breast cancer, small cell lung cancer, and non-Hodgkin's lymphoma). However, additional data in these

settings are needed and these results cannot be generalized to other disease settings and regimens absent specific trials. Dose-dense regimens should only be used within an appropriately designed clinical trial or if supported by convincing efficacy data.

Use of CSFs as Adjuncts to Progenitor-Cell Transplantation

Administration of CSFs to mobilize peripheral blood progenitor cells (PBPC), often in conjunction with chemotherapy and their administration after autologous, but not allogeneic, PBPC transplant is the current standard of care.

Use of CSFs in Patients with Leukemia or Myelodysplastic Syndromes

Initial or Repeat Induction Chemotherapy (AML)

Several studies have shown that CSF administration can produce modest decreases in the duration of neutropenia when begun shortly after completion of the initial induction chemotherapy. Beneficial effects on end points such as duration of hospitalization and incidence of severe infections have been variable and modest. CSF use following initial induction therapy is reasonable, although there has been no favorable impact on remission rate, remission duration or survival. Patients >55 years of age may be most likely to benefit from CSF use.

CSF for Priming Effects (AML)

Use of CSFs for priming effects is not recommended.

Consolidation Chemotherapy in AML

CSF use can be recommended after the completion of consolidation chemotherapy because of the potential to decrease the incidence of infection and eliminate the likelihood of hospitalization in some patients receiving intensive post remission chemotherapy. There seems to be more profound shortening of the duration of neutropenia after consolidation chemotherapy for patients with AML in remission than for patients receiving initial induction therapy. There is no effect on the duration of complete response duration or overall survival. There is, as yet, no information about the effect of longer acting, pegylated CSFs in patients with myeloid leukemias and they should not be used in such patients outside of clinical trials.

Myelodysplastic Syndrome (MDS)

No change from 2000 Update. CSFs can increase the absolute neutrophil count (ANC) in neutropenic patients with MDS. Data supporting the routine long-term continuous use of CSFs in these patients are lacking. Intermittent administration of CSFs may be considered in a subset of patients with severe neutropenia and recurrent infection.

Acute Lymphocytic Leukemia (ALL)

CSFs are recommended after the completion of the initial first few days of chemotherapy of the initial induction or first post remission course, thus shortening the duration of neutropenia of <1000/mm³ by approximately one week. There are less consistent effects on the incidence and duration of hospitalization and the acquisition of serious infections. Although there was a trend for improved complete response (CR) rates in one large study particularly in older adults, there was no prolongation of disease-free or overall survival in any of the trials. Granulocyte colony-stimulating factor (G-CSF) can be given together with the continued corticosteroid/antimetabolite therapy, which is a feature of many ALL regimens, without evidence that such concurrent therapy prolongs the myelosuppressive effects of the chemotherapy. As in AML, it is unknown from the published data whether the CSFs significantly accelerate recovery to neutrophil counts of 100-200/mm³. In most patients, regenerating counts of this level are sufficient to protect against infection so as to permit safe discharge of patients from the hospital. The use of G-CSF for children with ALL was associated with small benefits in days of antibiotics or in-hospital days, although a small amount of additional costs was incurred, after taking into consideration the costs of the CSFs. Cost estimates of CSFs for adults with ALL have not been reported.

Leukemia in Relapse

CSFs should be used judiciously, or not at all, in patients with refractory or relapsed myeloid leukemia since the expected benefit is only a few days of shortened neutropenia. Because of the relatively low response rate in AML patients with relapsed or refractory disease clinicians may be faced with the difficult dilemma of whether the persistence of leukemia after chemotherapy is a consequence of drug resistance or a stimulatory effect of the CSF. Although drug resistance is the most likely cause of treatment failure, it is sometimes necessary to stop the CSF and observe the patient for a few days to be certain. No significant change from 2000 recommendation.

Use of CSFs in Patients Receiving Radiation Therapy

CSFs should be avoided in patients receiving concomitant chemotherapy and radiation therapy, particularly involving the mediastinum. In the absence of chemotherapy, therapeutic use of CSFs may be considered in patients receiving radiation therapy alone if prolonged delays secondary to neutropenia are expected.

Use of CSFs in Older Patients

Prophylactic CSF for patients with lymphoma aged 65 and older treated with curative chemotherapy (CHOP or more aggressive regimens) should be given to reduce the incidence of febrile neutropenia and infections.

Use of CSFs in the Pediatric Population

The use of G-CSF in pediatric patients will almost always be guided by clinical protocols. As in adults, the use of G-CSF is reasonable for the primary prophylaxis of pediatric patients with a likelihood of FN. Similarly, the use of G-CSF for secondary prophylaxis or for therapy should be limited to high-risk patients. However, the potential risk for secondary myeloid leukemia or MDS associated

with G-CSF represents a concern in children with ALL whose prognosis is otherwise excellent. For these reasons, the specific use of G-CSF in children with ALL should be considered carefully.

CSF Initiation, Dosing, Duration and Administration

G-CSF (Filgrastim)

G-CSF should be given 24 to 72 hours after the administration of myelotoxic chemotherapy. In the setting of high-dose therapy and autologous stem cell rescue G-CSF can be given between 24 to 120 hours after administration of high-dose therapy. G-CSF should be continued until reaching an ANC of at least 2 to 3 x 10^9 /L. For PBPC mobilization, G-CSF should be started at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis.

Pegylated G-CSF (Pegfilgrastim)

Pegfilgrastim 6 mg should be given once, 24 hours after completion of chemotherapy. Pegfilgrastim is not currently indicated for stem cell mobilization. The safety and efficacy of pegylated G-CSF has not yet been fully established in the setting of dose-dense chemotherapy.

GM-CSF (Sargramostim)

Because GM-CSF has been licensed specifically for use after autologous or allogeneic bone marrow transplantation and for AML, the manufacturer's instructions for administration are limited to those clinical settings. GM-CSF should be initiated on the day of bone marrow infusion and not less than 24 hours from the last chemotherapy and 12 hours from the most recent radiotherapy. GM-CSF should be continued until an ANC greater than $1.5 \times 10^9/L$ for 3 consecutive days is obtained. The drug should be discontinued early or the dose be reduced by 50% if the ANC increases to greater than $20 \times 10^9/L$.

Dosing

G-CSF (filgrastim) and GM-CSF (sargramostim): In adults, the recommended CSF doses are 5 micrograms/kg/day for G-CSF and 250 micrograms/m²/day for GM-CSF for all clinical settings other than PBPC mobilization. In the setting of PBPC mobilization, if G-CSF is used, a dose of 10 micrograms/kg/day seems preferable. The preferred route of G-CSF administration is subcutaneous.

Pegylated G-CSF: Pegylated G-CSF (pegfilgrastim 6 mg) is given once in each chemotherapy cycle. The 6 mg formulation should not be used in infants, children, or small adolescents weighing <45 kg.

Special Comments on Comparative Clinical Activity of G-CSF and GM-CSF

No change. No guideline recommendation can be made regarding the equivalency of the two colony-stimulating agents. As in 2000, further trials are recommended to study the comparative clinical activity, toxicity, and cost-effectiveness of G-CSF and GM-CSF.

Special Comments on Growth factors as a Treatment for Radiation Injury

Current recommendations for the management of patients exposed to lethal doses of total body radiotherapy, but not doses high enough to lead to certain death due to injury to other organs, includes the prompt administration of CSF or pegylated G-CSF. Accidental or intentional (e.g., resulting from a terrorist attack or war) total body radiation leads to probable or certain death from bone marrow failure at doses of 3 to 10 Grays (Gy) without supportive care, CSFs, and/or a bone marrow transplant. Doses below that level are almost always survivable with excellent nursing care and higher doses are lethal because of injury to other organs such as the gastrointestinal tract. The chance for mortality from any radiation dose rises with combined injuries to the skin, lungs, etc. Hematopoietic growth factors can increase the survival, proliferation, amplification, and differentiation of granulocyte progenitors to produce neutrophils. Although no prospective, randomized trials have been carried out to determine the benefit of hematopoietic growth factors in humans exposed to accidental or intentional radiation injury, they have been utilized in radiation accident victims and neutrophil recovery appears to have been hastened in 25 of 28 cases (REACT/TS registry). In animal models, prompt administration of hematopoietic growth factors after otherwise lethal total body radiation exposure dramatically increases survival.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Significant reductions in the risk of febrile neutropenia (FN) and the risk of infection-related mortality.
- Reasonable use of colony-stimulating factors (CSF) to preserve effectiveness but discourage excess use when little marginal benefit is anticipated.

POTENTIAL HARMS

 Colony-Stimulating Factors (CSF) as an adjunct to progenitor cell transplantation: CSF used after allogeneic transplantation have been reported to increase the incidence of severe graft-versus-host disease and to reduce survival. Although rare, reports of splenic rupture and severe thrombocytopenia have been documented after use of filgrastim, lenograstim, and sargramostim for peripheral blood progenitor cell mobilization. Bone

- marrow transplant patients who received G-CSF also had a lower overall survival and lower leukemia-free survival.
- Because of the relatively low response rate in acute myeloid leukemia (AML)
 patients with relapsed or refractory disease, clinicians may be faced with the
 difficult dilemma of whether the persistence of leukemia after chemotherapy
 is a consequence of drug resistance or a stimulatory effect of the CSF.

CONTRAINDICATIONS

CONTRAINDICATIONS

Colony-stimulating factors should be avoided in patients receiving concomitant chemotherapy and radiation therapy, particularly involving the mediastinum. Clinical data do not allow for a definitive conclusion.

QUALIFYING STATEMENTS

QUALLEYING STATEMENTS

Guidelines and technology assessments cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonable directed at obtaining the same results. Accordingly, the American Society of Clinical Oncology (ASCO) considers adherence to this technology assessment to be voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances. In addition, this technology assessment describes the use of procedures and therapies in clinical practice; it cannot be assumed to apply to the use of these interventions performed in the context of clinical trials, given that clinical studies are designed to evaluate or validate innovative approaches in a disease for which improved staging and treatment is needed. In that guideline and technology assessment development involve a review and synthesis of the latest literature, a practice guideline or technology assessment also serves to identify important questions and settings for further research.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED QUALITY TOOLS

- American Society of Clinical Oncology (ASCO) Patient Guide: White Blood Cell Growth Factors
- White Blood Cell Growth Factors: 2006 Update. American Society of Clinical Oncology (ASCO) Clinical Practice Guideline Slide Set

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Smith TJ, Khatcheressian J, Lyman GH, Ozer H, Armitage JO, Balducci L, Bennett CL, Cantor SB, Crawford J, Cross SJ, Demetri G, Desch CE, Pizzo PA, Schiffer CA, Schwartzberg L, Somerfield MR, Somlo G, Wade JC, Wade JL, Winn RJ, Wozniak AJ, Wolff AC. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol 2006 Jul 1;24(19):3187-205. [128 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1994 Nov (revised 2006 Jul 1)

GUI DELI NE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology (ASCO)

GUIDELINE COMMITTEE

2006 ASCO White Blood Cell Growth Factors Guideline Update Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Thomas J. Smith (Chair); James Khatcheressian; Gary H. Lyman; Howard Ozer; James O. Armitage; Lodovico Balducci; Charles L. Bennett; Scott B. Cantor; Jeffrey Crawford; Scott J. Cross; George Demetri; Christopher E. Desch; Philip A. Pizzo; Charles A. Schiffer; Lee Schwartzberg; Mark R. Somerfield; George Somlo; James C. Wade; James L. Wade; Rodger J. Winn; Antoinette J. Wozniak; Antonio C. Wolf

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following authors or their immediate family members indicated a financial interest.

Authors	Employment	l eadership	Consultant	Stock	Honoraria	Research Funds	Testir
Thomas J. Smith*		23333131117					
James Khatcheressian*							
Gary H. Lyman			Amgen (B); Sanofi- Aventis (A)		Amgen (B); Sanofi- Aventis (A); Abraxis (A)	Amgen (C); Genomic Health (C); GlaxoSmithKline (B)	
Howard Ozer			Amgen (B); Sanofi- Aventis (A)		Amgen (B); Sanofi- Aventis (A); Abraxis (A)	Amgen (B); Sanofi-Aventis (B); Genentech (B)	
James O. Armitage			Amgen (A)				
Howard Balducci*							
Charles L. Bennett			Amgen (A)		Amgen (A)	Amgen (B)	
Scott B. Cantor*							
Jeffrey Crawford			Amgen (A)		Amgen (A)	Amgen (B)	
Scott J. Cross*							

Authors	Employment	l eadershin	Consultant	Stock	Honoraria	Research Funds	Testir
George Demitri	Employment	Leader Simp	Johnson & Johnson (A); Amgen (A)		Johnson & Johnson (A); Amgen (A)	Tunus	Johns Johr (N
Christopher E. Desch*							
Philip A. Pizzo*							
Charles A. Schiffer*							
Lee Schwartzberg					Amgen (A)	Amgen (B)	
Mark R. Somerfield*							
George Somla			Amgen (A)			Amgen (B)	
James C. Wade*							
James L. Wade*							
Rodger J. Winn*							
Antoinette J. Wozniak				Amgen (B)			
Antonio C. Wolff*							
Dollar	Amount Code	s (A) <\$10,0	00 (B) \$10,0	00–99,0	000 (C) <u><</u> \$1	00,000 (N/R) N	ot Requ

No conflict exists for drugs or devices used in a study if they are not being evaluated as part of the investigation. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Ozer H, Armitage JO, Bennett CL, Crawford J, Demetri GD, Pizzo PA, Schiffer CA, Smith TJ, Somlo G, Wade JC, Wade JL, Winn RJ, Wozniak AJ, Somerfield MR. 2000 update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based, clinical practice guidelines. American Society of Clinical Oncology Growth Factors Expert Panel. J Clin Oncol 2000 Oct 15;18(20):3558-85.

GUIDELINE AVAILABILITY

^{*} There are no disclosures to report.

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Clinical Oncology (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; E-mail: quidelines@asco.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

White blood cell growth factors: 2006 update. Slide set. Alexandria (VA):
 American Society of Clinical Oncology; 2006. 28 p. Electronic copies:
 Available in Portable Document Format (PDF) from the <u>American Society of Clinical Oncology (ASCO) Web site</u>.

PATIENT RESOURCES

The following is available:

• ASCO patient guide: white blood cell growth factors. 2006 May. Electronic copies available from the <u>American Society of Clinical Oncology Web site</u>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on September 1, 1998. It was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on December 1, 2000, to reflect the information published in the 2000 update of the original guideline (2000 update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based, clinical practice guidelines. J Clin Oncol 2000 Oct; 15[18]: 3558-85). The updated information was verified by the guideline developer as of December 20, 2000. This NGC summary was updated again by ECRI on July 27, 2006.

COPYRIGHT STATEMENT

This summary is based on the original guideline, which is subject to the American Society of Clinical Oncology's copyright restrictions.

DISCLAIMER

The National Guideline Clearinghouse[™] (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 10/2/2006